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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket No. 95 F-0255]

Indirect Food Additives: Paper and Paperboard Components

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of diallyl maleate and 1 -ethynyl- 1 -cyclohexanol as optional polymerization inhibitors and dimethyl (methyl hydrogen) polysiloxane as a cross-linking agent in the manufacture of vinyl-containing siloxanes that are used in coatings for paper and paperboard that contact food; to increase the maximum permitted residual level of platinum, which remains from the catalyst used in the manufacture of vinyl-containing siloxanes, to 200 parts per million (ppm) of these siloxanes; and to expand the safe use of coatings with vinyl-containing siloxanes for contact with additional food types and under additional conditions of use. This action is in response to a petition filed by GE Silicones.

DATES: The regulation is effective (insert *date of publication in the* **Federal Register);** written objections and requests for a hearing by *(insert date* 30 *days after date of publication in the* **Federal Register).**

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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FOR FURTHER INFORMATION CONTACT: Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3089.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of September 25, 1995 (60 FR 49414), FDA announced that a food additive petition (FAP 5B4475) had been filed by GE Silicones, c/o 700 13th St. NW., Washington, DC 20005. The petition proposed to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods (21* CFR 176.170) to provide for the safe use of vinyl-containing siloxanes as a component of coatings for paper and paperboard in contact with food and to provide for the safe use of 1-ethynyl- 1 -cyclohexanol as an optional inhibitor for the additive. The petition also proposed that the regulations be amended to increase the level of platinum catalyst used in the manufacture of vinyl-containing siloxanes to 200 ppm. In a notice published in the **Federal Register** of September 5, 1996 (61 FR 46814), FDA amended the September 25, 1995, notice to indicate that upon further review of the petition, the agency noted that the petitioner also proposed approval of the use of diallyl maleate as an optional polymerization inhibitor and dimethyl (methyl hydrogen) polysiloxane as a cross-linking agent in the manufacture of vinyl-containing siloxanes used in coatings on paper and paperboard that contact food. In addition, the agency clarified that the petitioner proposed to expand the safe use of coatings with vinyl-containing siloxanes for contact with additional food types and under additional conditions of use.

In the filing notices, the agency inadvertently stated that the petition proposed to increase the level of platinum catalyst used in the manufacture of vinyl-containing siloxanes. The petition actually proposed to increase the maximum permitted residual level of platinum in the vinyl-containing siloxanes, which is consistent with the existing regulation.

FDA has evaluated the data in the petition and other relevant material. The agency finds that the proposed use of the additives diallyl maleate and 1 -ethynyl- 1 -cyclohexanol as optional polymerization inhibitors and the proposed use of the additive dimethyl (methyl hydrogen)

polysiloxane as a cross-linking agent in the manufacture of vinyl-containing siloxanes intended for use as a component of coatings for paper and paperboard in contact with food are safe and achieve their intended technical effects. Finally, the agency concludes that the resulting vinyl-containing siloxanes are safe and will have their intended technical effects. Therefore, the regulations in §176.170 should be amended as set forth below.

In accordance with § 171. l(h) (21 CFR 171. l(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before (insert *date 30 days after date of publication in the* **Federal Register), file** with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each

numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 176

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegate to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 176 is amended as follows:

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

1. The authority citation for 21 CFR part 176 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 346, 348, 379e.

2. Section 176.170 is amended in the table in paragraph (b)(2) by revising the first entry for ‘ ‘Siloxanes and silicones” under the headings “List of substances” and “Limitations” to read as follows:

§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

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(b) * * *

(2) * * *

List of substances	Limitations
Siloxanes and silicones: platinum-catalyzed reaction product of vinyl-containing dimethylpolysiloxane (CAS Reg. Nos. 68083-19-2 and 68083-18-1) with methyl hydrogen polysiloxane (CAS Reg No 6314957-2) or dimethyl (methyl hydrogen) polysiloxane (CAS Reg. No. 68037-59-2), Diallylmaleate (CAS Reg No, 99%21-3). dimethyl maleate (CAS Reg No 624–48–6), 1 -ethynyl - 1 -cyclohexanol (CAS Reg. No. 78–27–3) and vinyl acetate (CAS Reg. No 108–05–4) may be used as optional polymerization inhibitors.	For use only as a surface coating Platinum content not to exceed 200 parts per million.

* * * * *

Dated: 12/4/98

December 4, 1998

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

L. Robert Lake

L. Robert Lake
Director
Office of Policy, Planning and Strategic Initiatives
Center for Food Safety and Applied Nutrition

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